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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,932	07/18/2003	Subhashis Banerjee	BPI-187	3572

959 7590 05/23/2007

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EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	**PAPER NUMBER**
1643	
MAIL DATE	**DELIVERY MODE**
05/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,932	BANERJEE ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 3 and 15-17 have been cancelled.

2. Claims 1-2, 4-11 and 13 have been amended.

3. Claims 1-2 and 4-14 are under consideration to the extent that the TNFα-related disorder or skin disorder is psoriasis, i.e., the elected species.

Objections/Rejections Withdrawn

4. The objection to the specification in the use of various trademarks is withdrawn in view of applicants' arguments.

5. The objection to claims 1-2 and 4-14 as being drawn to non-elected inventions and as depending from withdrawn claim 3 is withdrawn in view of the cancellation of claim 3.

6. The objection to claim 11 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in view of applicants' arguments.

7. The rejection of claim 13 under 35 U.S.C. 101 because the claim does not set forth any steps involved in the process and thus, is not a proper process claim under 35 U.S.C. 101 is withdrawn in view of the amendments to the claim.

8. The rejection of claim 13 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is withdrawn in view of the amendments to the claim.

9. The rejection of claims 7, 11 and 14 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is withdrawn in view of applicants' arguments, i.e., D2E7 is also known as HUMIRA® and adalimumab and is readily available to the public or commercially available.

10. The rejection of claims 1-2 and 13 under 35 U.S.C. 102(b) as being anticipated by Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000) is withdrawn in view of applicants' argument and amendments to the claims, which require a human TNFα antibody.

11. The rejection of claims 1-2 and 13 under 35 U.S.C. 102(b) as being anticipated by Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001) is withdrawn in view of applicants' argument and amendments to the claims, which require a human TNFα antibody.

12. The provisional rejection of claims 1-2 and 4-14 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 14-27 and 29 of copending Application No. 10/622,205 is withdrawn in view of the abandonment of copending Application No. 10/622,205.

Objections/Rejections Maintained

13. The objection to the specification as disclosing various non-provisional US Application numbers whose status has changed and require updating is maintained.

The response filed 3/6/2007 states that Applicants have reviewed and to the best of Applicants' knowledge the status of the disclosed non-provisional applications are up to date. This has been fully considered but is not found persuasive. USSN 10/302,356 at pg. 1, line 13, pg. 7, lines 4 and 19 and pg. 8, line 16 needs to be updated as "now abandoned". Similarly, USSN 10/133,715 at pg. 1, line 14 should be updated as "now abandoned". Additionally, Applicant should update the status of the US Application numbers in the second paragraph beginning at pg. 1, line 17 (e.g., see amendment filed 4/16/2004) given that many of the disclosed applications are "now abandoned". It is noted that USSN 09/801,185 (e.g., pg. 1, line 12) has been allowed and should be updated with the corresponding US Patent number during the pendency of the present application. Applicants' cooperation is again requested in reviewing the entire

disclosure for additional non-provisional U.S. Application Numbers that require updating.

Appropriate correction is required.

14. The objection to the title of the invention as not descriptive or clearly indicative of the invention to which the claims are directed is maintained.

The response filed 3/6/2007 requests that this objection be held in abeyance until final disposition and allowance of the claims. This has been fully considered but is not found persuasive. The claims in the present application are not in condition for allowance and the objection is maintained. Applicant should restrict the title to the treatment of psoriasis using human TNFα antibodies.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. The rejection of claims 5, 9 and 12 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating psoriasis in a subject comprising administering a human anti-human TNFα antibody or antigen-binding fragment thereof comprising a light chain comprising CDR1 of SEQ ID NO:7, CDR2 of SEQ ID NO:5 and CDR3 of SEQ ID NO:3 comprising the recited amino acid substitutions and a heavy chain comprising CDR1 of SEQ ID NO:8, CDR2 of SEQ ID NO:6 and CDR3 of SEQ ID NO:4 comprising the recited amino acid substitutions, does not reasonably provide enablement for a method of treating psoriasis in a subject comprising administering a human anti-human TNFα antibody or antigen-binding fragment thereof comprising a light chain comprising CDR3 of SEQ ID NO:3 comprising the recited amino acid substitutions and a heavy chain comprising a heavy chain comprising CDR3 of SEQ ID NO:4 comprising the recited amino acid substitutions as

broadly encompassed by the claims is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The response filed 3/6/2007 argues that in the method of claims 5, 9 and 12, the human antibody or antigen-binding fragment thereof must not only have specific heavy and light chain CDR3 sequences, but must also dissociate from human TNFα with a K_{off} of 1×10^{-3} s^{-1} or less, as determined by surface plasmon resonance. Applicant cites MPEP 2164.06, which indicates that the quantity of experimentation is only one factor involved in determining whether "undue experimentation" is required and a considerable amount of experimentation is permissible. Applicant also cites MPEP 2164.08(b), which states that the presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. Applicant refers to pp. 18-20 of the specification, which teaches that the heavy and light chain CDR3 domains play an important role in the binding specificity/affinity of an antibody for an antigen and that the CDR3 domains of the light and heavy chain sequences of antibody D2E7 have advantageous properties for use in the invention. Applicants' arguments have been fully considered but are not found persuasive. The scope of the claims remains extremely broad, encompassing human antibodies and antigen-binding fragments thereof that only comprise the CDR3 domains from human anti-TNFα antibody D2E7. For example, the claims encompass human antibodies and antigen-binding fragments thereof that comprise a heavy chain CDR1 from a human antibody that binds HER2, a heavy chain CDR2 from a human antibody that binds EPO, a light chain CDR1 from a human antibody that binds EGFR, and a light chain CDR2 from a human antibody that binds CD30 in combination with the recited D2E7 CDR3 domains, wherein the antibodies dissociate from human TNFα with a K_{off} of 1×10^{-3} s^{-1} or less, as determined by surface plasmon resonance. Again, the teachings and exemplification provided in the specification are limited to human anti-human TNFα antibodies and antigen-binding fragments thereof that comprise all six CDRs, three from the heavy chain and three from the light chain of human anti-human TNFα antibody D2E7, which does not provide

adequate guidance and direction to assist those skilled in the art in making and using the broader genus of human antibodies and antigen-binding fragments thereof that only comprise the CDR3 domains of D2E7 and which dissociate from human TNFα with a K_{off} of 1×10^{-3} s^{-1} or less, as determined by surface plasmon resonance. The argument as essentially set forth indicates no disclosure of the genus is necessary, no guidance to make the human antibodies and antigen-binding fragments is required because the skilled artisan can make and test using art recognized techniques to discover how best to practice the claimed invention. This is not persuasive because the issue is make and use, not make and test to see if the skilled artisan could use. The specification does not enable the genus because where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one particular species, what other species will work. See MPEP 2164.03. The art also points out that changing the complementary determining regions is a hit and miss proposition and even minor changes in the amino acid sequences of heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidence by Rudikoff et al (Proc. Natl. Acad. Sci. USA, 79:1979-1983, 1982; of record). Rudikoff et al teach that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma antibody resulted in the loss of antigen-binding function. Finally, it was well established in the art that the CDRs have a particular order, particular length and that the formation of an intact antigen-binding site of most antibodies routinely requires the association of the complete heavy and light chain variable regions of an antibody each of which consists of three CDRs or hypervariable regions presented in a specific order, which provide the majority of the contact residues for the binding of the

antibody to its target epitope (Paul ed. Fundamental Immunology, 3rd Edition, 1993, pp 292-295, of record).

Applicants' arguments regarding the fact that not all of the CDRs of an antigen binding site may be necessary in binding a specific antigen and the significance of the CDR3 domains of antibody D2E7 are acknowledged, however, all of the antibody fragments with which applicant argues with the exception of an isolated CDR and a dAb fragment, which consists of the VH domain comprise all of the heavy and light chain CDRs of an antibody in their proper order and in the context of framework sequences which maintain their correct spatial orientation and have the requisite antigen binding function. There is insufficient description and evidence that an antigen-binding fragment which only comprises the CDR3 domains of antibody D2E7 binds human TNFα with a K_{off} of 1×10^{-3} s^{-1} or less, as determined by surface plasmon resonance. Further, while there are some publications, which acknowledge that CDR3 is important, the conformations of other CDRs as well as framework residues influence binding. MacCallum et al (J. Mol. Biol., 262, 732-745, 1996) analyzed many different antibodies for interactions with antigen and state that although CDR3 of the heavy and light chain dominate, a number of residues outside the standard CDR definitions make antigen contacts (see page 733, right col.) and non-contacting residues within the CDRs coincide with residues as important in defining canonical backbone conformations (see page 735, left col.). The fact that not just one CDR is essential for antigen binding or maintaining the conformation of the antigen binding site, is underscored by Casset et al (Biochemical and Biophysical Research Communications, 307:198-205, 2003), which constructed a peptide mimetic of an anti-CD4 monoclonal antibody binding site by rational design and the peptide was designed with 27 residues formed by residues from 5 CDRs (see entire document). Casset et al also states that although CDR H3 is at the center of most if not all antigen interactions, clearly other CDRs play an important role in the recognition process (page 199, left col.) and this is demonstrated in this work by using all CDRs except L2 and additionally using a framework residue located just before the H3 (see page 202, left col.). The issue remains the description of the claimed human antibody variants and guidance and direction of the specification for the claimed

variants encompassing just any CDR1 and CDR2 domains in combination with the CDR3 domains of human antibody D2E7. The issue is not make and test, it is not the art that must provide the description to enable the genus of human antibodies and antigen-binding fragments thereof, but Applicants.

The examiner acknowledges applicants remarks regarding US Patent No. 6,090,382, however, applicant is reminded that each US Patent application is examined on its own merits and the examiner is precluded from commenting on an issued patent.

In view of the lack of the predictability of the art to which the invention pertains as evidenced by Paul W. E., Rudikoff et al, MacCallum et al and Casset et al, the lack of guidance and direction provided by applicant, and the absence of working examples, undue experimentation would be required to practice the claimed human antibody variants that bind human TNFα with a K_{off} of 1×10^{-3} s^{-1} or less, as determined by surface plasmon resonance for the treatment of psoriasis in a subject, with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed human antibodies and absent working examples providing evidence which is reasonably predictive that the claimed human antibody variants bind human TNFα with a K_{off} of 1×10^{-3} s^{-1} or less, as determined by surface plasmon resonance, commensurate in scope with the claimed invention.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. The rejection of claims 1-2, and 4-14 under 35 U.S.C. 103(a) as being unpatentable over Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000) in view of Salfeld et al [a] (WO 97/29131, publication date 8/14/1997) is maintained.

The response filed 3/6/2007 states that Oh et al teach treating psoriasis with a chimeric anti-TNFα antibody (Infliximab), but do not teach the claimed neutralizing, high affinity human TNFα antibody, i.e., D2E7/HUMIRA, and Salfeld et al [a] teach treating rheumatoid arthritis with the claimed neutralizing, high affinity human TNFα antibody, but do not teach treating psoriasis. Applicant also argues that there is no suggestion or motivation either in the references or in the knowledge generally available to one of ordinary skilled in the art to modify or combine the teachings in the prior art to arrive at the claimed invention, i.e., treatment of a skin disorder, and in particular psoriasis in a patient comprising administering a neutralizing, high affinity human TNFα antibody. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention

where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art would have been motivated to modify the method of Oh et al using the human anti-human TNFα antibodies and antigen-binding fragments thereof of Salfeld et al [a] (i.e., identical to the claimed antibodies) in order to avoid any unwanted immune reaction in human patients due to the presence of murine sequences in the chimeric anti-TNFα antibody of Oh et al. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. *In re Semaker*, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references and the rejection is maintained.

19. The rejection of claims 1-2, and 4-14 under 35 U.S.C. 103(a) as being unpatentable over Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000) in view of Salfeld et al [b] (US Patent 6,509,015 B1, 2/9/1996) is maintained.

Applicant argues as above, with the exception of Salfeld et al [b] in place of Salfeld et al [a] (Salfeld et al [a] and Salfeld et al [b] are equivalents) and the examiner's remarks above apply here as well and are incorporated herein by reference.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references and the rejection is maintained

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. The rejection of claims 1-2 and 4-14 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 16, 36-39, 48 and 69-70 of U.S. Patent No. 6,509,015 B1 in view of Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000) is maintained.

The response filed 3/6/2007 argues that claims 1-7, 16, 36-39, 48 and 69-70 of U.S. Patent No. 6,509,015 B1 are limited to the treatment of rheumatoid arthritis and Oh et al teach treating psoriasis with a chimeric anti-TNFα antibody (Infliximab), but do not teach the claimed neutralizing, high affinity human TNFα antibody, i.e., D2E7/HUMIRA. This has been fully considered, but is not found persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness

is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). It is reiterated that, one of ordinary skill in the art would have been motivated and had a reasonable expectation of success at the time the invention was made to modify the therapeutic method of claims 1-7, 16, 36-39, 48 and 69-70 of U.S. Patent No. 6,509,015 B1 for the treatment of psoriasis in a human patient because Oh et al teach the administration of an anti-TNFα antibody effectively treats psoriasis in a human patient. Thus, there would be a therapeutic advantage to using the neutralizing, high affinity human TNFα antibodies, i.e., D2E7/HUMIRA according to claims 1-7, 16, 36-39, 48 and 69-70 of U.S. Patent No. 6,509,015 B1 in subjects suffering from psoriasis.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 6,509,015 B1, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

22. The provisional rejection of claims 1-2 and 4-14 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 and 73-84 of copending Application No. 10/163,657 in view of Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000) is maintained.

The response filed 3/6/2007 argues that claims 1-23 and 73-84 of copending Application No. 10/163,657 are limited to the treatment of rheumatoid arthritis with a biweekly dose of human anti-TNFα antibodies and Oh et al teach treating psoriasis with a chimeric anti-TNFα antibody (Infliximab), but do not teach the claimed neutralizing, high affinity human TNFα antibody, i.e., D2E7/HUMIRA. This has been fully considered, but is not found persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). It is reiterated that, one of ordinary skill in the art would have been motivated and had a reasonable expectation of success at the time the invention was made to modify the therapeutic method of claims 1-23 and 73-84 of copending Application No. 10/163,657 for the treatment of psoriasis in a human patient because Oh et al teach the administration of an anti-TNFα antibody effectively treats psoriasis in a human patient. Thus, there would be a therapeutic advantage to using the neutralizing, high affinity human TNFα antibodies, i.e., D2E7/HUMIRA according to claims 1-23 and 73-84 of copending Application No. 10/163,657 in subjects suffering from psoriasis.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common

ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 10/163,657, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

23. The provisional rejection of claims 1-2 and 4-14 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 15 of copending Application No. 11/233,252 in view of Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000) and Salfeld et al [a] (WO 97/29131, publication date 8/14/1997) is maintained.

The response filed 3/6/2007 states that copending Application No. 11/233,252 claims a method of treating a patient with rheumatoid arthritis and other diseases, but not a skin disorder, and psoriasis with anti-TNFα antibodies and for the reasons stated above Oh et al and Salfeld et al [a] (WO 97/29131) do not teach or suggest the claimed method. Applicants' arguments have been fully considered but are not found persuasive. The examiners' arguments above for Oh et al and Salfeld et al [a] apply here as well, are incorporated herein and the rejection is maintained.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 11/233,252, discussed above, would form the basis for a rejection of the noted claims

under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

24. The provisional rejection of claims 1-2 and 4-14 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5,7-26 and 28-53 of copending Application No. 11/104,117 in view of Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000) is maintained.

The response filed 3/6/2007 requests that the present rejection be held in abeyance until final disposition and allowance of the claims in the instant application. Applicant's arguments have been fully considered but are not found persuasive because the present claims are not in condition for allowance.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 11/104,117, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that

the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

25. No claims are allowed.

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Blanchard
Primary Examiner
Art Unit 1643

DB
May 14, 2007